

## REMARKS

### Claims

Claims 1–5 are currently under examination. Claims 6–8, which were withdrawn due to restriction/election are hereby cancelled without prejudice or disclaimer. Applicant reserves the right to file one or more divisional applications to withdrawn cancelled subject matter.

Claims 9–18 are added by this paper.

### Amendments

The claims have been amended in accordance with conventional US practice.

Amendment to claim 1 is supported by the disclosure contained in, for example, page 5, lines 18–31 and the disclosure contained in Example 1 of the originally-filed specification.

Previously withdrawn claims 6–8 have been cancelled to purely facilitate prosecution. No agreement to the restriction requirement and/or rejection(s) is to be implied.

The subject matter cancelled from claim 4 is now presented in new claim 9.

New claims 10–18 are directed to further aspects of the claimed methods. Support for claims can be found in, for example, page 2, lines 2-4, and page 4, lines 30-32 and the disclosure contained in the Examples.

It is respectfully submitted that the claim amendments do not raise new matter.

### Objections

The objection of the specification is noted. Applicants' specification provides a detailed description of the various reagents and/or applications recited in the instant specification, including names and addresses of all the vendors and/or suppliers, which provide such tools/reagents. At the time the instant application was filed, the skilled worker was endowed with replete knowledge pertaining to reagents and/or applications recited in the specification. For example, the specification provides adequate description of the dyes PicoGreen and RiboGreen (which are available via Molecular Probes) along with MagIPrep (available via Merck KGaA). With respect to Tween 20, which is commonly recognized as polysorbate 20 (polyoxyethylen(20)-sorbitan-monolaurat) and Triton X-100 (polyethylene glycol p-(1,1,3,3-tetramethylbutyl)-phenyl ether), it is submitted that these claim terms are definite to a skilled molecular biologist. A quick search on PUBMED can verify that the meaning(s) conveyed by these terms is generically understood in the filed of molecular biology. Withdrawal of the rejection is

respectfully requested.

### **Rejection under 35 U.S.C. §112, ¶2**

Applicants thank the Examiner for his careful review of the claims. The rejection, not specifically discussed herein, is moot in view of the amendments. Withdrawal of the rejection is respectfully requested.

In view of the aforementioned remarks and arguments, Applicants respectfully submit that the claim language is sufficiently definite, especially in the context of Applicants' instant specification and the information available to the skilled worker prior to the filing of the instant application. Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 U.S.C. §102**

The contention that Gundling's disclosure (US patent publication no. 2002/0068821; published: June 6, 2002) anticipates claims 1-3, 6 and 8 of the present application is respectfully traversed.

In levying the anticipation rejection, the Examiner alleges that Gundling's use of metal oxide support layer comprising magnetite in isolation of RNA anticipates the present claims. While such may be the case; however, this disclosure alone is insufficient for anticipation. It is submitted that for anticipation, the reference, either explicitly or inherently, teach all the elements of the claimed invention. The PTO has not established that all features of present method claims are disclosed in Gundling. For example, the reference is silent with respect to the utilization of a binding buffer comprising phosphate. The Office Action very vaguely contends that such aspects are disclosed in examples 1 and 2 of Gundling. However, this contention is misplaced. The reference does not disclose a binding buffer containing phosphate and additionally, the RNA samples used in example 1 and 2 seem to be non-natural samples so there should not be any phosphate present. In Gundling, phosphate-containing buffers are only used as elution buffers. See, for example, paragraphs [0031] and [0034] of the '821 publication. In any case, no hint is given in Gundling that the presence of phosphate could have any effect on the binding properties of RNA. Compare this with Applicants' disclosure in Example 1 and 2 of the present application. The experimental evidence therein demonstrates very clear that increased and efficient binding of RNA is achieved with a phosphate-based buffer, and more importantly, RNA molecules are preferentially bound compared to DNA molecules. See, new claim 10.

Gundling is silent with respect to the preferential RNA binding, as claimed herein. In Gundling, both RNA and DNA are bound. This is explicitly taught in paragraphs [0009] and [0010] of the

publication. The cited reference and the method disclosed therein do not discriminate between these two nucleic acid species. Gundling does not teach or suggest methods for discriminating RNA vs. DNA and/or that the reagents could be optimized for the isolation of RNA molecules.

#### **Rejections under §103(a)**

Claims 4 and 7 are rejected under §103(a) as allegedly unpatentable over the aforementioned Gundling publication and Madden (US publication No. 2005/0054847; filed July 30, 2004). Claim 5 is resjected under the same section as allegedly being unpatentable over Gundling in view of Kilaas' disclosure in WO 2004/003231. With respect to the rejection of claims 4 and 7, the Office Action contends that the utilization of EDTA in the claimed RNA extraction process is taught by Madden. With respect to the rejection of claim 7, the Examiner alleges that the claimed aspect of utilizing magnetic particles in the RNA extraction process is taught by Kilaas. These allegations, and the rejections based thereon, are respectfully traversed.

The failure of primary Gundling reference to teach each and every element of Applicants' claimed invention have been established *supra*. For example, the primary reference is absolutely silent regarding the use of phosphate based binding buffers and the selectivity of the reagents in isolating RNA molecules, as presently claimed. Madden is directed to methods for preparing nucleic acids of a defined size (see ABSTRACT). Nothing is said in Madden about the isolation of RNA and/or methods for selective isolation of RNA in the presence of DNA. Madden adds nothing to what is not taught by Gundling. As such, the two disclosures, even at their broadest interpretation, fail to render obvious the claims of the instant application. The PTO's allegations with respect to the chelating agents used in Madden are misplaced insofar as Madden only generically teaches that chelating agents are suitable for the preparation process. The cited reference offers no suggestion or motivation to utilize such in a manner disclosed by the present application. For example, the usefulness of such reagents in selective isolation of RNA molecules from a mixed pool of nucleic acids is not taught therein.

Kilaas provides further details about magnetic particles and such, but neither Gundling nor Kilaas offers any hint as to the unexpected utility thereof in selective isolation of RNA in the presence of DNA. As such, the rejection is without merit.

Withdrawal of the rejection and passage to allowance is earnestly solicited.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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